PATENT

Attorney Docket No. 227833 Client Reference No. JF-133US

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Sunami et al.

Group Art Unit: 1614

Application No. 10/802,220

Examiner: Unassigned

Filed: March 17, 2004

For: PHARMACEUTICAL COMPOSITIONS

OF CETP INHIBITORS

#### INFORMATION DISCLOSURE STATEMENT

Mail Stop Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

within any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date

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		st Office Action on the merits; or (d) before the mailing of a first Office Action the filing of a request for continued examination under 37 CFR 1.114.
	37 CFÌ	a), (b), (c) or (d) above, but before the mailing date of a final action under R 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that ise closes prosecution in the application, and includes <i>one</i> of:
		the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
	$\Box$	the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
	under 3 and or 37 CFI	the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance 37 CFR 1.311, or an action that otherwise closes prosecution in the application, in or before payment of the issue fee, and includes the Statement under R 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as the in 37 CFR 1.17(p) (see "Fees" below).
	payme: contair 37 CFI \$180 a NOTE: May 29,	the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before int of the issue fee, and within thirty days of receiving each item of information need in the Information Disclosure Statement, and includes the Statement under R 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of set forth in 37 CFR 1.17(p) (see "Fees" below).  This is for original applications except applications for a design patent, filed on or after 2000, wherein a paper containing only an Information Disclosure Statement in compliance CFR 1.97 and 1.98 is being filed.
Copie	s of the	References
	Copies herewi	of all of the references listed on the enclosed Form 1449 are enclosed th.
$\boxtimes$	patents enclose	atent application was filed after June 30, 2003. Accordingly, copies of U.S. and patent applications that are listed on the accompanying Form 1449 are not ed herewith (see Official Gazette Notice of August 5, 2003). Copies of other acces identified on the accompanying Form 1449 are enclosed herewith.
	relevar an Eng action degree	ed to each reference not in the English language is a concise explanation of the nce pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or glish-language abstract, or an English-language version of the search report or by a foreign patent office in a counterpart foreign application indicating the of relevance found by the foreign office is being submitted in lieu of a concise ation of the relevance pursuant to 37 CFR 1.98(a)(3).
$\boxtimes$	A copy	y of the foreign search report is enclosed herewith.
		eferences listed on the enclosed Form 1449 were previously identified in the

In re Appln. of Sunami et al. Application No. 10/802,220

furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLI	CATIONS	Status (check one)			
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED	
1.					
2.					
3.					

State	ment under 37 CFR 1.97(e)
	The <b>undersigned</b> hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
	The <b>undersigned</b> hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.
State	ment under 37 CFR 1.704(d)
	The <b>undersigned</b> hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
Fees	
$\boxtimes$	No fee is owed by the applicant(s). The IDS Fee of \$180 under 37 CFR 1.17(p) is enclosed herewith.

In re Appln. of Sunami et al. Application No. 10/802,220

Metho	d of Payment of Fees				
	Attached is a check in the amount of \$ Charge Deposit Account No. 12-1216 in the amount of \$ this communication is enclosed for that purpose.)  (A duplicate copy of				
Autho	rization to Charge Additional Fees				
$\boxtimes$	If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)				
Instru	ctions as to Overpayment				
	Credit Account No. 12-1216. Refund  John Kilyk, Jr., Reg No 36,763 LEYDIG, VOIT & MAYER, LTD. Two Prudential Plaza, Suite 4900 180 North Stetson Avenue Chicago, Illinois 60601-6780 (312) 616-5600 (telephone)				
Date:	(312) 616-5700 (facsimile) October 8, 2004				
	CERTIFICATE OF MAILING				
States envelo	I hereby certify that this INFORMATION DISCLOSURE STATEMENT (along with cuments referred to as being attached or enclosed) is being deposited with the United Postal Service on the date shown below with sufficient postage as first class mail in an pe addressed to: Mail Stop , Commissioner for Patents, P.O. Box 1450, Alexandria, 313-1450.				

IDS (Revised 5/21/03)

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Substitute for form 1449A/B/PTO CT 1 2 2004	Application Number	10/802,220	
INFORMATION DISELOSURE	Filing Date	March 17, 2004	
INFORMATION DISCLOSURES STATEMENT BY APPENDANT	First Named Inventor	Sunami et al.	
STATEMENT BY APPENDAM	Group Art Unit	1614	
(Use as many sheets as necessary)	Examiner Name	Unassigned	
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Sheet

LVM Reference Number

Attorney Docket Number

227833

JF-133US

				U.S. PATENT DOCUMENTS		
		U.S. Patent Do	cument			
Examiner Initials	Doc. No.	Application or Patent Number	Kind Code	Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
	ΑI	3,576,830		Fukumaru et al.	Apr. 27, 1971	
	AJ	4,740,438		Krishnamurthy	Apr. 26, 1988	
	AK	4,853,319		Krishnamurthy et al.	Aug. 1, 1989	
	ΑL	5,118,583	Α	Kondo et al.	Jun. 2, 1992	
	AM	5,194,539	Α	Charmot et al.	Mar. 16, 1993	
	AN	5,217,859	Α	Boettcher et al.	Jun. 8, 1993	
	ΑO	5,219,721	Α	Klaus et al.	Jun. 15, 1993	
-	AP	5,350,667	Α	Singer et al.	Sep. 27, 1994	
	AQ	5,405,969	Α	Wright et al.	Apr. 11, 1995	
	AR	5,446,207	Α	Pomponi et al.	Aug. 29, 1995	
	AS	5,504,097	Α	Malamas et al.	Apr. 2, 1996	
	ΑТ	5,512,548	Α	Kushwaha et al.	Apr. 30, 1996	
	ΑU	5,519,001	Α	Kushwaha et al.	May 21, 1996	
	ΑV	5,534,529	Α	Yoshida et al.	Jul. 9, 1996	
	AW	5,542,974	Α	Buding	Aug. 6, 1996	
	AX	5,556,888	Α	Koda et al.	Sep. 17, 1996	
	ΑY	5,614,550	Α	Yoshida et al.	Mar. 25, 1997	
	ΑZ	5,654,134	Α	Morimura et al.	Aug. 5, 1997	
	ВА	5,698,564	Α	Katsuyama et al.	Dec. 16, 1997	
	BB	5,776,951	Α	Arrowsmith et al.	Jul. 7, 1998	
	ВС	5,880,095	Α	Park et al.	Mar. 9, 1999	
	ВD	5,925,645	Α	Schmidt et al.	Jul. 20, 1999	
1	BE	5,932,587	Α	Schmeck et al.	Aug. 3, 1999	
	BF	6,069,148	Α	Schmidt et al.	. May 30, 2000	
	ВG	6,093,573	Α	Beamer et al.	Jul. 25, 2000	
	вн	6,127,383	Α	Schmidt et al.	Oct. 3, 2000	
	ВΙ	6,140,342	Α	Goldstein et al	Oct. 31, 2000	
	BJ	6,140,343	Α	DeNinno et al.	Oct. 31, 2000	
	BK	6,147,089	Α	DeNinno et al.	Nov. 14, 2000	
	BL	6,147,090	Α	DeNinno et al.	Nov. 14, 2000	
	ВМ	6,197,786	B1	DeNinno et al.	Mar. 6, 2001	
	BN	6,207,671	B1	Schmidt et al.	Mar. 27, 2001	
	ВО	6,313,142	B1	Damon et al.	Nov. 6, 2001	
	BP	6,362,198	B1	Goldstein et al.	Mar. 26, 2002	
	BQ	6,395,751	B1	DeNinno et al.	May 28, 2002	
	BR	6,448,295	B1	Sikorski et al.	Sep. 10, 2002	
	BS	6,462,091	B1	Keller et al.	Oct. 8, 2002	
	ВТ	6,753,346	B2	Shinkai et al.	Jun. 22, 2004	

Examiner Signature Date Considered

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

<sup>+</sup> An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Substitute for form 1449A/B/PTO

# **INFORMATION DISCLOSURE** STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	4

Complete if Known			
Application Number	10/802,220		
Filing Date	March 17, 2004		
First Named Inventor	Sunami et al.	-	
Group Art Unit	1614		
Examiner Name	Unassigned		
LVM Reference Number	227833		
Attorney Docket Number	JF-133US		

				U.S. PATENT DOCUMENTS		
U.S. Patent Document						
Examiner Initials	Doc. No.	Application or Patent Number	Kind Code	Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
	ВU	2001/0018446	A1	Sikorski et al.	Aug. 30, 2001	
	BV	2002/0103225	A1	Curatolo et al.	Aug. 1, 2002	
	BW	2004/0039018	A1	Ruggeri	Feb. 26, 2004	
	вх	2004/0053842	A1	Nguyen et al.	Mar. 18, 2004	

				FORE	IGN PATENT DOCUMENTS			
Foreign Patent Document			oreign Patent Documen	it			Trans	slation
Examiner Initials	Doc. No.	Office	Application or Patent Number	Kind Code	Name of Patentee or Applicant	Date of Publication	Yes	No*+
	ΒY	CA	2,000,631	Α	Engels	Apr. 15, 1990		
	ΒZ	ES	2 127 690	B1	Universidad de Granada	Apr. 16, 1999		X <sup>+</sup>
	CA	EP	0 796 846	A1	BAYER AG	Sep. 24, 1997		X⁺
	СВ	EP	0 818 197	A1	BAYER AG	Jan. 14, 1998		X⁺
	СС	EP	0 818 448	A1	BAYER AG	Jan. 14, 1998		X⁺
	CD	JP	45-11132		Sumitomo Chemical Company	Apr. 22, 1970		X⁺
	CE	JP	47-35786		Oouchi-Shinkou-Chemical Company	Sep. 8, 1972		X <sup>+</sup>
	CF	JP	1-321432		Konica Corp.	Dec. 27, 1989		X⁺
	ĊG	JP	1-278543		Sanshin Kagaku Kogyo KK	Nov. 8, 1989		X <sup>+</sup>
	СН	JP	2-23338		Fuji Photo Film Co., Ltd.	Jan. 25, 1990		X <sup>+</sup>
	СІ	JP	3-226750		Konica Corp.	Oct. 7, 1991		X <sup>+</sup>
	CJ	JP	9-59155	A2	KAKEN PHARMACEUTICAL CO LTD	Mar. 4, 1997		X⁺
	СК	JP	10-287662	A2	THE KITASTO INSTITUTE	Oct. 27, 1998		X⁺
	CL	wo	92/03408	A1	RHONE-POULENC RORER LIMITED	Mar. 5, 1992		
	СМ	wo	92/03412	A2	RHONE-POULENC RORER LIMITED	Mar. 5, 1992		
	CN	WO	96/30761	A1	WARNER-LAMBERT COMPANY	Oct. 3, 1996		
	СО	WO	96/09406	A1	UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES	Mar. 28, 1996		
	CP	WO	98/04528	A2	BAYER CORPORATION	Feb. 5, 1998		
	CQ	WO	98/04528	A3	BAYER CORPORATION	Nov. 11, 1999		
	CR	WÓ	98/23593	A1	PFIZER INC.	Jun. 4, 1998		
	CS	wo	98/34920	A1	BAYER AKTIENGESELLSCHAFT	Aug. 13, 1998		X⁺
	СТ	WO	98/35937	A1	JAPAN TOBACCO INC.	Aug. 20, 1998		X⁺
	CU	wo	98/39299	A1	BAYER AKTIENGESELLSCHAFT	Sep. 11, 1998		X⁺
	CV	wo	99/14204	A1	G.D. SEARLE & CO.	Mar. 25, 1999		
	cw	wo	99/41237	A1	G.D. SEARLE & CO.	Aug. 19, 1999		

Examiner Signature		Date Considered	

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-	FOREIGN PATENT DOCUMENTS							
Examiner Doc.			Foreign Patent Document  Application or Kind		-		Frans	slation
Initials	Doc. No.	Office	Patent Number	Kind Code	Name of Patentee or Applicant	Date of Publication	Yes	No*+
	СХ	wo	99/50454	A2	WHITEHEAD INSTITUTE FOR	Oct. 7, 1999		
					BIOMEDICAL RESEARCH			
	CY	wo	00/18721	A1	MONSANTO COMPANY	Apr. 6, 2000		
	CZ	wo	00/18723	A1	MONSANTO COMPANY	Apr. 6, 2000		
	DA	WO	00/18724	A1	MONSANTO COMPANY	Apr. 6, 2000		
	DB	WO	00/38721	A1	G.D. SEARLE & CO.	Jul. 6, 2000		
	DC	wo	00/38722	A1	G.D. SEARLE & CO.	Jul. 6, 2000		
	D D	wo	00/38723	A1	G.D. SEARLE & CO.	Jul. 6, 2000		
	DE	wo	00/38724	A1	G.D. SEARLE & CO.	Jul. 6, 2000		
	DF	WO	00/38725	A1	G.D. SEARLE & CO.	Jul. 6, 2000		
	DG	· WO	00/38726	A1	G.D. SEARLE & CO.	Jul. 6, 2000		
	DH	WO	00/53792	A1	THE KITASATO INSTITUTE	Sep. 14, 2000		X⁺
	DΙ	wo	01/18250	A2	WHITEHEAD INSTITUTE FOR	Mar. 15, 2001		
					BIOMEDICAL RESEARCH			
ļ	DJ	wo	01/18250	A3	WHITEHEAD INSTITUTE FOR	Jul. 25, 2002		
		14/0		<b></b>	BIOMEDICAL RESEARCH			
	DK	WO	01/40190	A1	PFIZER PRODUCTS INC.	Jun. 7, 2001		
	DL	WO	01/56579	A1	ESPERION THERAPEUTICS INC.	Aug. 9, 2001		<u> </u>
	DM	WO	02/11710	A2	PFIZER PRODUCTS INC.	Feb. 14, 2002		
	DN	WO	02/11710	A3	PFIZER PRODUCTS INC.	May 2, 2002		> / +
	DO	wo	02/59077	A1	TAKEDA CHEMICAL INDUSTRIES, LTD.	Aug. 1, 2002		X⁺
	DP	wo	03/000295	A2	PFIZER PRODUCTS INC.	Jan. 3, 2003		
	DQ	wo	03/000295	A3	PFIZER PRODUCTS INC.	May 27, 2004		
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First Named Inventor	Sunami et al.		
Group Art Unit	1614		
Examiner Name	Unassigned		
LVM Reference Number	227833		
Attorney Docket Number	JF-133US		

	OTHER - NON PATENT LITERATURE DOCUMENTS  Varniner   Doc   Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item			Translation	
Examiner Initials	Doc. No.	(hook magazine journal serial symposium catalog etc.) date page(s) volume issue number (s) publisher			
	DR	ANTONOVA et al., Comptes rendus de l'Academie bulgare des Sciences, 46(1), 71-74 (1993)	Х		
	DS	CONNOLLY et al., Biochemical and Biophysical Research Communications, 223(1), 42-47 (1996)			
	DT	DE GROOTH et al., XIV International Symposium on Drugs Affecting Lipid Metabolism, 47 (2001)			
	DU	DE GROOTH et al., Circulation, Supplement II, 104(17), 848 (2001)			
	DV	DROZD, Zhurnal Organicheskoi Khimii, 23(2), 355-365 (1987)	X		
	DW	EGAN et al., Advances in Prostaglandin, Thromboxane, and Leukotriene Research, 11, 151-157 (1983)			
	DX	HORI et al., Heterocycles 9(10), 1413-1418 (1978)			
	DY	HUANG et al., Clinical Science, 103(6), 587-594 (2002)			
	DΖ	MAEDA et al., Bioorganic & Medicinal Chemistry Letters, 14, 2589-2591 (2004)			
	EΑ	NAGARAJAN et al., Indian Journal of Chemistry, 12(3), 227-235 (1974)			
	EВ	OKAMOTO, Lipid, 13(1), 76-81 (2002)		X,	
	EC	OKAMOTO, BIO Clinica, 18(5), 429-432 (2003)		X,	
	ED	OKAMOTO et al., European Journal of Pharmacology, 466(1-2), 147-154 (2003)			
	EE	SHIMOJI et al., Atherosclerosis, 172(2), 247-257 (2004)			
	EF	SHINKAI, <i>Naibunpi, Tonyobyoka, 12(4),</i> 364-369 (2001)	<u></u>	X,	
	EG	SIMOV et al., Khimiya Geterotsiklicheskikh Soedinenii, 9, 1192-1195 (1976)	*	X,	
	EH	WAKITANI et al., The Knowledge Foundation's 2 <sup>nd</sup> International Conference on HDL Cholesterol Metabolic Pathways and Drug Development, 1 (2001)			
	ΕI	WATTS, Clinical Science, 103(6), 595-597 (2002)		$\Box$	
	EJ	WCN Working Group on Cardiovascular Research, Slide Presented at the 15 <sup>th</sup> Annual Scientific WCN Meeting, Amsterdam, The Netherlands (December 2002)	-		
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